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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and MERCK SHARP & DOHME LLC, Plaintiffs, v. HIKMA PHARMACEUTICALS USA INC., Defendants.	Civil Action No. 24-3206 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Merck Sharp & Dohme LLC ("Merck LLC") (together, "Merck"), by their attorneys, bring this complaint against Defendant Hikma Pharmaceuticals USA Inc. ("HUSA") and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of HUSA's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration

("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the 2mg/200 mL strength of a purported generic version of Bridion® (sugammadex) Injection prior to the expiration of U.S. Patent No. RE44,733 ("the RE'733 patent").

PARTIES

2. Plaintiff Merck B.V. is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. Merck B.V. is an indirect, wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 126 East Lincoln Avenue, P.O. Box 2000, Rahway, New Jersey 07065 .

3. Plaintiff Merck LLC, which holds approved New Drug Application No. 022225 for Bridion®, is a limited liability company formed and existing under the laws of New Jersey, having its corporate offices and principal place of business at 126 East Lincoln Avenue, P.O. Box 2000, Rahway, New Jersey 07065. Merck LLC is a direct, wholly owned subsidiary of Merck & Co., Inc.

4. On information and belief, Defendant HUSA is a Delaware corporation, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

5. By a letter dated February 2, 2024 ("HUSA's Notice Letter"), HUSA notified Merck that HUSA had submitted to the FDA ANDA No. 218727 ("HUSA's ANDA") for a purported generic version of sugammadex sodium EQ 200 mg base/2 ml solution ("HUSA ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the HUSA ANDA Product in or into the United States, including New Jersey, prior to the expiration of the RE'733 patent.

6. On information and belief, HUSA knows and intends that upon FDA approval of HUSA's ANDA, it will manufacture, promote, market, sell, offer for sale, import, use, and/or

distribute the HUSA ANDA Product throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

7. Merck incorporates each of the preceding paragraphs 1–6 as if fully set forth herein.

8. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the asserted patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over HUSA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, HUSA's principal place of business is in Berkeley Heights, New Jersey. HUSA's website states that its "US Headquarters" is located at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. *See* https://www.hikma.com/contact/us-locations/ (last visited, February 13, 2024).

10. On information and belief, HUSA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 100487525. On information and belief, HUSA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5002130.

11. On information and belief, HUSA derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in various generic pharmaceutical products sold throughout the United States, including in this judicial district.

12. HUSA is also subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, HUSA develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic

drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

13. HUSA specifically directed HUSA's Notice Letter to Merck LLC's headquarters in Rahway, New Jersey, in this judicial district.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to HUSA, because, on information and belief, HUSA has a regular and established place of business in New Jersey, and because, on information and belief, HUSA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patent that will lead to foreseeable harm and injury to Merck by preparing or assisting in preparing HUSA's ANDA in New Jersey with the intention of seeking to market the HUSA ANDA Product nationwide, including within New Jersey.

THE PATENT-IN-SUIT

15. Merck B.V. is the owner and assignee of the RE'733 patent, entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block" (attached as Exhibit A). Merck B.V. has the right to enforce the RE'733 patent.

16. The RE'733 patent resulted from an application for reissue of U.S. Patent No. 6,670,340 (the "'340 patent"), which was duly and legally issued on December 30, 2003. The '340 patent was duly and legally reissued as the RE'733 patent on January 28, 2014.

17. The RE'733 patent includes claims that recite 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, compositions containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, methods of using 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, and kits containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin.

18. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

19. On February 4, 2020, the United States Patent and Trademark Office ("PTO") issued a Notice of Final Determination on the patent term extension ("PTE") application for the RE'733 patent, wherein the PTO determined that the RE'733 patent is eligible for 5 years of PTE (attached as Exhibit B). The PTE certificate issued, and the expiration of the RE'733 patent is January 27, 2026 (attached as Exhibit C). The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") currently lists the expiration of the RE'733 patent as January 27, 2026.

20. In *In re Sugammadex*, Civil Action No. 20-2576 (CCC) (LDW), the consolidated defendants contested the validity of a portion of the PTE granted by the PTO. This Court found that the extension of the RE'733 patent's term after December 14, 2022 is not invalid and that the RE'733 patent does not expire until January 27, 2026, as previously determined by the PTO. Dkt. Nos. 418, 419, 423. The consolidated defendants' appeal of that judgment to the Federal Circuit is pending in *Merck, Sharp & Dohme B. V. v. Aurobindo Pharma USA*, No. 23-2254 (Fed. Cir.).

THE BRIDION® DRUG PRODUCT

21. Merck LLC is the holder of New Drug Application ("NDA") No. 022225, under which the FDA approved the commercial marketing of Bridion® (sugammadex) Injection ("Bridion®") on December 15, 2015, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). Bridion® is approved for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. Bridion® is distributed in the United States by Merck Sharp and Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., in 200 mg/2 mL and 500 mg/5 mL strengths in a single-dose vial for bolus injection. A true and correct copy of the current prescribing

information for Bridion® is attached as Exhibit D.

22. Bridion® is a first-in-class drug that works differently than prior agents used for the reversal of neuromuscular blockade. The active ingredient in Bridion®, sugammadex, is a modified cyclodextrin that acts by directly encapsulating, binding, and inactivating agents used by healthcare providers to induce neuromuscular blockade in patients undergoing surgery, e.g., rocuronium or vecuronium, to reverse their effects. After intravenous injection, Bridion® distributes through plasma and binds to such neuromuscular blocking agents ("NMBAs") to form a complex. This process reduces the amount of NMBA available to bind to nicotinic cholinergic receptors in the neuromuscular junction, resulting in the reversal of neuromuscular blockade.

23. By this mechanism, Bridion® also avoids several of the side effects associated with prior reversal agents, such as acetylcholinesterase inhibitors. Traditional reversal agents are co-administered with other agents to manage these side effects, but the co-administered agents can cause a number of additional side effects. Moreover, Bridion® is capable of reversing the complete and prolonged block of neuromuscular function (known as "profound block") that can occur with the administration of NMBAs. Further, intravenous administration of sugammadex results in more rapid recovery from moderate or deep neuromuscular blockade in patients undergoing surgery who received rocuronium or vecuronium, as compared to neostigmine or succinylcholine. Because of at least these unique features, Bridion® has been viewed as a significant advance in the field of anesthesiology.

24. Bridion®, as well as methods of using Bridion®, are covered by one or more claims of the RE'733 patent. The RE'733 patent has been listed in connection with NDA No. 022225 in the FDA's Orange Book.

HUSA'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

25. On information and belief, HUSA has submitted or caused the submission of HUSA's ANDA to the FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the HUSA ANDA Product, as a purported generic version of Bridion®, prior to the expiration of the RE'733 patent.

26. On information and belief, the FDA has not yet approved HUSA's ANDA.

27. In HUSA's Notice Letter, HUSA notified Merck of the submission of HUSA's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the HUSA ANDA Product prior to the expiration of the RE'733 patent.

28. In HUSA's Notice Letter, HUSA acknowledged that the Reference Listed Drug for HUSA's ANDA is Bridion®. Bridion® is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

29. In HUSA's Notice Letter, HUSA stated that the HUSA ANDA Product contains sugammadex as an active ingredient.

30. In HUSA's Notice Letter, HUSA acknowledged that the Court in *In re Sugammadex*, Civil Action No. 20-2576, found in Merck's favor on the issue of the proper calculation of patent term extension but asserted that the district court erred in doing so.

31. In HUSA's Notice Letter, HUSA notified Merck that, as part of its ANDA, HUSA had filed a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the RE'733 patent.

32. On information and belief, HUSA submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the RE'733 patent is

invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the HUSA ANDA Product .

33. On information and belief, HUSA, through its own actions and through the actions of its agents, affiliates, and subsidiaries, prepared and submitted HUSA's ANDA, and intend to further prosecute HUSA's ANDA. On information and belief, if the FDA approves HUSA's ANDA, HUSA will manufacture, offer for sale, or sell the HUSA ANDA Product within the United States, or will import the HUSA ANDA Product into the United States. On information and belief, if the FDA approves HUSA's ANDA, HUSA, through its own actions and through the actions of its agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the HUSA ANDA Product in or into the United States.

34. Merck brings this action within forty-five days of receipt of HUSA's Notice Letter. Accordingly, Merck is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE RE'733 PATENT

35. Merck incorporates each of the preceding paragraphs 1–34 as if fully set forth herein.

36. The HUSA ANDA Product, and the use of the HUSA ANDA Product, is covered by one or more claims of the RE'733 patent, including at least claim 1 of the RE'733 patent, because claim 1 of the RE'733 patent encompasses the sugammadex utilized in the HUSA ANDA Product.

37. In HUSA's Notice Letter, HUSA did not contest infringement of the claims of the the RE'733 patent. If HUSA had a factual or legal basis to contest infringement of those claims of the RE'733 patent, then it was required by applicable regulations to state such a basis in HUSA's Notice Letter. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed,

claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug as to which the applicant has submitted a Paragraph IV Certification).

38. HUSA's submission of HUSA's ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the HUSA ANDA Product in or into the United States before the expiration of the RE'733 patent is an act of infringement of the RE'733 patent under 35 U.S.C. § 271(e)(2)(A).

39. If approved by the FDA, HUSA's commercial manufacture, use, importation, sale, and/or offer for sale of the HUSA ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the RE'733 patent under 35 U.S.C. § 271(a)-(c).

40. On information and belief, HUSA will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the HUSA ANDA Product in or into the United States immediately and imminently upon approval of HUSA's ANDA.

41. The commercial manufacture, use, sale, offer for sale, or importation of the HUSA ANDA Product in or into the United States would infringe one or more claims of the RE'733 patent.

42. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the HUSA ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the RE'733 patent.

43. On information and belief, upon FDA approval of HUSA's ANDA, HUSA will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market

and/or distribute the HUSA ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, HUSA will knowingly and intentionally accompany the HUSA ANDA Product with a product label or product insert that will include instructions for using or administering the HUSA ANDA Product, which are substantially similar to the instructions in the prescribing information for Bridion®, attached as Exhibit D, and which, if followed, will infringe the RE'733 patent. Accordingly, HUSA will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the HUSA ANDA Product to directly infringe the RE'733 patent. On information and belief, HUSA will encourage acts of direct infringement with knowledge of the RE'733 patent and knowledge that HUSA are encouraging infringement.

44. On information and belief, HUSA plans and intends to, and will, actively induce infringement of the RE'733 patent when HUSA's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. HUSA's activities will be done with knowledge of the RE'733 patent and specific intent to infringe that patent.

45. On information and belief, HUSA knows that the HUSA ANDA Product and proposed labeling are especially made or adapted for use in infringing the RE'733 patent, that the HUSA ANDA Product are not a staple article or commodity of commerce, and that the HUSA ANDA Product and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, HUSA plans and intends to, and will, contribute to infringement of the RE'733 patent immediately and imminently upon approval of HUSA's ANDA.

46. Notwithstanding HUSA's knowledge of the claims of the RE'733 patent, HUSA has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import the HUSA ANDA Product with its product labeling in or into the United States following FDA

approval of HUSA's ANDA prior to the expiration of the RE'733 patent.

47. The foregoing actions by HUSA constitute and/or will constitute direct infringement of the RE'733 patent; active inducement of infringement by others of the RE'733 patent; and contribution to the infringement by others of the RE'733 patent.

48. Merck will be substantially and irreparably damaged by infringement of the RE'733 patent. Unless HUSA is enjoined from directly infringing the RE'733 patent, actively inducing infringement of the RE'733 patent, and contributing to the infringement of the RE'733 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and HUSA, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the RE'733 patent has been infringed under 35 U.S.C. § 271(e)(2) by HUSA's submission to the FDA of HUSA's ANDA;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the HUSA ANDA Product, or any other drug product that infringes or the use of which infringes the RE'733 patent, be not earlier than the expiration date of the RE'733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining HUSA, and all persons acting in concert with HUSA, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the HUSA ANDA Product, or any other drug product covered by or whose use is covered by the RE'733 patent, prior to the expiration of the RE'733 patent, inclusive

of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the HUSA ANDA Product, or any other drug product that is covered by or whose use is covered by the RE'733 patent, prior to the expiration of the RE'733 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to the infringement by others of the RE'733 patent;

(e) A declaration that HUSA's commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the HUSA ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the RE'733 Patent by HUSA under one or more of 35 U.S.C. § 271(a), (b), and (c);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if HUSA engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the HUSA ANDA Product, or any product that infringes the RE'733 patent, or induces or contributes to such conduct, prior to the expiration of the RE'733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that HUSA willfully and deliberately infringed the RE'733 patent;

(h) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: March 15, 2024
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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